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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,109	08/20/2003	Jean-Marie Stutzmann	USST98048USDIV1	6531

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EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,109	STUTZMANN ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 18, 2004 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claim 8 has been canceled.

2. Claims 1 and 2 have been amended.

3. Remarks drawn to rejections under 35 U.S.C. 112, first and second paragraph and 103(a).

Claims 1-7 and 9-19 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Objections

The objection to claim 8 has been overcome by cancellation of the claim.

Claim 2 is objected to because of the following informalities: The term treating is recited twice. Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7 and 9-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 and 9-19 of copending Application No. 10/644150. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 34 of U.S. Patent No. 6,608,042 ('042 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claim 1 is drawn to a method of increasing the survival or growth of motoneurons comprising contacting the motoneurons with low molecular weight heparin. Claim 2 is drawn to a method for treating motoneuron diseases comprising administering an effective amount of low molecular weight heparin. Dependent claims 3-7 and 9-19 are drawn to specific motoneuron diseases and molecular weight ranges of the heparin.

Claim 34 of the copending '042 patent also recites a method for treatment of diseases linked to survival and growth of motoneurons using oligosaccharides that are heparins as evident from the structural formula recited in the claim.

It would be obvious to one of ordinary skill in the art that instant claims 1-7 and 9-19 and claim 34 of the copending '042 patent are substantially overlapping. Instant claims 1-7 and 9-19 should recite limitations that are patentably distinct over those of claim 34 of the copending '042 patent.

Claim Rejections - 35 USC § 112

The rejection of claims 2-19 under 35 U.S.C. 112, first paragraph as not enabling for the prevention of motoneuron disease has been overcome by deletion of the term preventing in claim 2.

The rejection of claims 1-19 has been overcome by amendment to claim 1 and documentation for use of alphanumeric notations in claims 18 and 19. The previous office action stated that claims 18 and 20 are rejected. This is a typographical error. It should have been claims 18 and 19.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lesma et al (Journal of Neuroscience Research, 1996, 46, 565-571) newly cited.

Claim 1 is drawn to a method of increasing the survival or growth of motoneurons comprising contacting the motoneurons with low molecular weight heparin.

Lesma et al teach that contacting neuroblastoma cells with low molecular weight heparin at low doses promoted neurite formation (page 567, Table I., entry two; page 567, left column, left column, lines 19-21; page 568, left column, 1-7; page 569, left column, lines 19-21; page 569, right column, 19-25). This teaching is seen to meet the limitations of instant claim 1.

Claims 2 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Von Arnim (WO 94/18988) newly cited.

Claim 2 is drawn to a method of treating a motoneuron disease comprising administering to a patient in need thereof an effective amount of low molecular weight heparin. Claim 12 is drawn to a method according to one of claims 1 to 3 wherein the low molecular weight heparin is reviparin.

Von Arnim teaches the treatment of multiple sclerosis using low molecular weight heparins (abstract, page 1, lines 1-11; page 29, lines 1-3). Multiple sclerosis belongs to a group of motor neuron disorders (see American Speech Language Hearing Association, 1997, page 1, lines 1-4). One of the low molecular weight heparins taught by Von Arnim for the treatment of multiple sclerosis is Reviparin (page 28, line 29 through page 29, line 2).

The teaching of Von Arnim is seen to meet the limitations of instant claims 2 and 12.

Claim Rejections - 35 USC § 103

The rejection of claims 1 and 3-19 as being unpatentable over Snow et al (WO 91/06303) has been overcome by applicant's remarks/arguments. The following art rejection is made of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Arnim (WO 94/18988) in combination with see American Speech Language Hearing Association, 1997, page 1, lines 1-4 and Lesma et al (Journal of Neuroscience Research, 1996, 46, 565-571) newly cited.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is drawn to a method of increasing the survival or growth of motoneurons comprising contacting the motoneurons with low molecular weight heparin. Claim 2 is drawn to a method for treating motoneuron diseases comprising administering an effective amount of low

molecular weight heparin. Dependent claims 3-7 and 9-19 are drawn to specific motoneuron diseases and molecular weight ranges of the heparin.

Von Arnim teaches the treatment of multiple sclerosis using low molecular weight heparins (abstract, page 1, lines 1-11; page 29, lines 1-3). Multiple sclerosis belongs to a group of motor neuron disorders (see American Speech Language Hearing Association, 1997, page 1, lines 1-4). One of the low molecular weight heparins taught by Von Arnim for the treatment of multiple sclerosis is Reviparin (page 28, line 29 through page 29, line 2).

However, Von Arnim does not teach the use of low molecular weight heparin in a method for the treatment of specific motoneuron diseases wherein the disease is amyotrophic lateral sclerosis, spinal muscular dystrophy, infantile muscular dystrophy or lateral sclerosis.

American Speech Language Hearing Association teaches that diseases amyotrophic lateral sclerosis, multiple sclerosis and muscular dystrophy all belong to the groups of motor neuron diseases that are characterized by gradual degeneration and death of motor neurons (page 1, lines 1-4).

Lesma et al teach that contacting neuroblastoma cells with low molecular weight heparin at low doses promoted neurite formation (page 567, Table I., entry two; page 567, left column, left column, lines 19-21; page 568, left column, 1-7; page 569, left column, lines 19-21; page 569, right column, 19-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use specific low molecular weight heparins in a method for the treatment of motoneuron diseases and in a method for increasing the survival or growth of motoneurons with a reasonable amount of success since the use of low molecular weight heparin for the treatment

of motor neuron diseases and the use of heparin for increasing the survival and growth of motoneurons is taught by the prior art of record.

One of ordinary skill in the art would be motivated to do so since Lesma et al teach that low molecular weight heparin is most effective for the growth and survial of motor neurons and Von Arnim teaches that low molecular weight heparin like Reviparin is effective for the treatment of motoneuron diseases like multiple sclerosis. One of ordinary skill in the art would be motivated to extend this to other low molecular weight heparins in the 1000-10000 daltons range in order to find other superior heparins for use in the methods as instantly claimed.

Claims 1-7 and 9-19 are rejected under 35 U.S.C. 103(a) as being obvious over Mourier et al (US 6608042).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this

rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim 1 is drawn to a method of increasing the survival or growth of motoneurons comprising contacting the motoneurons with low molecular weight heparin. Claim 2 is drawn to a method for treating motoneuron diseases comprising administering an effective amount of low molecular weight heparin. Dependent claims 3-7 and 9-19 are drawn to specific motoneuron diseases and molecular weight ranges of the heparin.

Mourier et al teach oligosaccharides of formula (I) that has all the structural features of heparin (Abstract, col. 14, lines 20-46). Mourier teaches a method of treating diseases linked to the survival and growth of motoneurons comprising administering an effective amount of the compound of formula (I) (col. 5, lines 10 through 21; col. 6, lines 8-38; col. 7, lines 32-34; col. 9, lines 55-58; col. 17, line 18 through col. 18 line 18). Since the number of repeating units n is an integer from 0 to 25, the molecular weight of the compound of formula (I) falls within the ranges recited in instant claims 4-6 and also the molecular weight ranges of the various heparins recited in instant claims 9-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use low molecular weight heparins in a method as instantly claimed since such a method is seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to use the art tested low molecular weight heparins in a method as instantly claimed since the oligosaccharides of formula (I) are

derived from heparin (col. 8, line 35 through col. 12, line 67) and very effective for the growth of motoneurons as seen by the reported 20-50% growth rate (col. 7, lines 32-34).

Conclusion

Claims 1-7 and 9-19 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

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